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Description

The present invention relates generally to a small, precision, passive one-way valve for medical applications which opens when a minimal pressure drop occurs across the valve, and is particularly adapted for use as an improved valve in a medical infusion pump.

In the past, two techniques have been used to deliver drugs which may not be orally ingested to a patient. The first is through an injection, or shot, which delivers a large dosage at relatively infrequent intervals to the patient. This technique is not always satisfactory, particularly when the drug being administered is lethal or has negative side effects when delivered in a large dosage. This problem results in small injections being given at more frequent intervals.

The second technique involves administering a continuous flow of medication to the patient through an IV (intravenous) bottle. Medication may also be delivered through an IV system with an injection being made into a complex maze of IV tubes, hoses, and other paraphenalia. As an alternative to these two techniques of administering medication to a patient, the recent addition of medication infusion pumps has come as a welcome improvement.

Infusion pumps are used to administer drugs to a patient in small, metered doses at frequent intervals or, alternatively, in the case of some devices, at a low but essentially continuous rate. Infusion pump therapy may be electronically controlled to deliver precise, metered doses at exactly determined intervals thereby providing a beneficial gradual infusion of medication to the patient. In this manner, the infusion pump is able to mimic the natural process whereby chemical balances are maintained precisely by operating on a continuous time basis.

One of the essential elements of an infusion pump is a one-way valve, one or more of which is required in virtually any design for an infusion pump. Such a valve must be highly precise, operating in a passive manner to open with a relatively small break pressure or cracking pressure in the desired direction of flow through the valve. The valve must also be resistant to a substantially higher reverse pressure, not opening or leaking at all, since any reverse flow in the opposite direction would result a reduction in the amount of medication being delivered, and an imprecise infusion pump which would be totally unacceptable.

The valve must be easily manufactured, and must have both an extended shelf life and a long operating life. It must also be made from a material which is a medical grade, and which will not be affected by any of the numerous medications which may be administered by the infusion pump.

An additional requirement has been imposed by the important design consideration of disposability. It is desirable that the pump portion of the infusion pump device be disposable, and therefore the valve must in addition to all the requirements previously mentioned be inexpensive, and must also be installable in the pump easily. Since the inexpensive nature of the disposable pump mandates against expensive moulding techniques, it is a primary object of the valve that it be installable in the pump with only one half of the housing containing the valve requiring a complex form. More specifically, the top or inlet portion of the housing should be flat save for an opening through which the medication being pumped may flow into contact with and through the valve.

It is also necessary, in order to minimise the number of parts required and therefore the cost of construction of the disposable pump, that sealing means be included in the integral design of the pump. When the two portions of the pump housing are assembled with the valve between them; fluid will be able to flow only through the valve, and not around it. In addition, leaks from the pump between the two portions of the housing will be prevented by the sealing means. One example of check valve of the prior art similar to that of the invention is disclosed in US-A- 2 758 609. This type of valve, however, does not meet all of the above mentioned requirements implied by the use of such a valve in the medical field. In particular this valve needs the support of a separate axial spring in order to ensure a positive sealing pressure of the disk against the seat.

According to the invention, there is provided a passive one way valve assembly member located between a first housing member having an outlet and a second housing member having an outlet, the valve member of one piece manufacture including a circular valve disc, a static seal ring surrounding the valve disc, and a resilient support means supporting the valve disc from the seal ring, characterised by an annular dynamic sealing ridge protruding from the top surface of the valve disc which engages the first housing member thereby deforming the resilient support means, the resilience of the support means in turn serving to bias the sealing ridge against the first housing member thereby closing the inlet.

The invention also extends to a valve construction incorporating such a valve located between upper and lower housing members, with the static sealing ring forming a seal between the housing members.

Thus, the disadvantages and limitations of the background art discussed above may be overcome by the present invention which provides an in-

expensive valve of unitary construction having sealing means integrally included which may be installed between two housing portions, one of which may be essentially flat with an aperture from which fluid flows into contact with and through the valve. Thus the valve may be installed in a flat-top configuration allowing the portion of the housing on top of the valve to be flat rather than precision contoured, thereby allowing a substantial reduction in the cost of the pump.

The invention may therefore provide a passive one way valve construction for a medication infusion system comprising an upper housing member, a lower housing member and a valve located between the two housing members and a valve as defined located between the two housing members, the upper housing member having a fluid inlet and a substantially flat surface in contact with the valve disc, and the lower housing member having a fluid outlet.

The valve may be moulded in a unitary fashion from a medical grade elastomer such as silicone rubber. The rubber may have a durometer hardness of between 30 and 70, preferably between 40 and 50 on the Shore A scale. Preferably, the valve disc is so arranged and configured as to be of a thickness sufficiently substantial to prevent the valve disc from exhibiting a significant amount of flexure even under high reverse pressure.

Preferably, the dynamic sealing ridge has a rounded top surface to enhance its sealing characteristics. The ridge, which effectively constitutes the actual valve element, preferably extends above the top of the valve disc by about 0.01ins (0.25mm).

Preferably, the support means is in the form of a relatively thin supporting web. Preferably the web extends from a location substantially at the top of the static seal ring to the valve disc at a height not exceeding the top of the valve disc.

Thus, the dynamic sealing ridge can extend above the support web and can act to bias the valve disc downwards when the flat surface of the upper housing member contacts the top of the seal ring.

Preferably, the valve is biased in a closed position until the forward pressure drop across the valve is at least 0.1 PSI (70.3kg/m^2). Preferably the valve is so arrange and configured as to minimise the volume of fluid which may be contained around the valve and between the upper and lower housing members. Preferably, the static seal ring is sufficiently large so as to be relatively rigid in supporting the valve disc.

Preferably, the support web has a plurality of apertures to allow the passage of fluid there through. There may for example be ten apertures arranged around the valve disc. The apertures may be so arranged and configured so as to reduce the amount of biasing force caused by prestressing of said support web. Preferably, the support means has a portion adjacent the static seal ring which is arranged to be supported by a web support portion of a lower housing member in use.

Preferably the valve has an outer diameter of between 0.2 and 0.75 ins (5.1 to 19.1mm). Preferably, the valve includes some means for preventing a large forward pressure across the valve from causing the valve disc to block or obstruct the outlet aperture in the lower housing portion. Such means may comprise at least one bump either extending below the bottom surface of the valve disc, or extending up from the lower support member, to prevent the bottom of the valve disc from obstructing the outlet aperture.

The valve may be installed by locating it in a first or lower housing member which has provision for receiving the static seal ring, and may also include a web support structure for supporting a portion of the web adjacent to the static seal ring. The first housing member has an aperture therein to allow fluid passing through the valve to exit, which aperture is located on the underside of the valve when it is installed in the first housing member as described above.

The second or upper housing member is then installed on top of the valve as previously installed in the first housing member portion. The second housing member, which rests on top of the valve, is essentially flat, and has an aperture therein through which fluid may enter towards the valve. This aperture is located above the valve disc and concentrically within the dynamic sealing ridge. When the second housing member is installed onto the first housing member with the valve therebetween, the static seal ring is compressed to create a good seal.

In operation, when the pressure is greater above the valve disc than below the valve disc, the valve will tend to open, requiring any a small pressure to operate. However, when this small break pressure is not present, or when a reverse pressure is present, the valve will remain in the closed position. It may thereby be appreciated that the valve has a very positive sealing action when closed, and that it will open easily when the small break pressure (or a greater pressure in that direction) is present.

It is apparent that the valve as described herein may be simply constructed in a single moulding operation in one piece, thereby minimising both parts and costs. The valve may be moulded of a medical grade elastomer, which is acceptable for use in an infusion pump, and may have an excellent shelf life and operating life characteristics.

As a result of the novel design of the valve, the portion of the housing mounted on the top side of the valve may be flat, and therefore of economical construction. Even so, an excellent seal is obtained, thereby preventing both leaks out of the pump and in either direction around the valve. Since the valve is highly precise and has only a small required break pressure to open it, it offers excellent operating characteristics. Finally, the economic construction of the valve and the resulting enablement of economic construction of the pump make the valve a valuable addition to the art, particularly for the construction of a disposable pump.

The invention may be carried into practice in various ways and some embodiments will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a plan view of the top side of the valve of the present invention;

Figure 2 is a cross-sectional view of the valve along the line 2-2 in Figure 1 illustrating the configuration of the valve;

Figure 3 is a plan view of the bottom side of the valve shown in Figures 1 and 2;

Figure 4 is a view of the valve shown in Figures 1 to 3 installed between first and second housing portions, with the valve in the closed position;

Figure 5 is a view of the valve of Figures 1 to 3 installed as shown in Figure 4 between the first and second housing portions, with the valve in an open position;

Figure 6 is a schematic block diagram of the operation of a pump using two of the valves of the present invention;

Figure 7 is a cross-sectional view of an alternative embodiment using valve stop ribs on the floor of the lower housing portion to prevent over travel by the valve disc rather than using bumps on the bottom side of the valve disc; and

Figure 8 is a cross-sectional view of the top side of the lower housing portion along the line 8-8 in Figure 7.

A possible configuration for an infusion pump using two of the valves of the present invention is illustrated schematically in Figure 6. Medication contained in a fluid source 10 is to be provided to a patient via a catheter 12, which is of standard design and well known in the art. The fluid driver may be generically described as a pump 14, which may be any of a number of different arrangements, the most common of which is a variable displacement piston and cylinder arrangement.

The pump 14 is driven by a pump driving mechanism 16, which may also be any of a number of different arrangements which are known for controlling an infusion pump. Two one-way valves 18A, 18B are used to control the pumping force generated by the pump 14. The first one-way valve 18A is located in the fluid path between the fluid source 10 and the pump 14, and will only allow fluid to pass from the fluid source 10 to the pump 14. The second one-way valve 18B is located between the pump 14 and the catheter 12, and will only allow fluid to pass from the pump 14 to the catheter 12.

When the displacement of the pump 14 is increasing, fluid will be drawn into the pump 14. Since the second valve 18B will not allow fluid to flow into the pump 14, fluid will be drawn from the fluid source 10 through the first valve 18A into the pump 14. Likewise, when the displacement of the pump 14 is decreasing, fluid will be forced out from the pump 14. Since the first valve 18A will not allow fluid to flow out from the pump 14, fluid will be forced out from the pump 14 through the second valve 18B into the catheter.

For a disposable pump, the two valves 18A and 18B, and the pump 14 would be the disposable components (presumably together with the associated tubing, the catheter, and the empty fluid source). The present invention focuses on the construction of the valves 18A and 18B, which are usually identical. It will be appreciated by one skilled in the art that the present invention may be adapted to have application in virtually any infusion pump conceivable.

Referring now to Figures 1 to 3, a valve 20 is illustrated which is constructed according to the teachings of the present invention. Basically, the valve 20 consists of three elements, the first of which is a rigid valve disc 22 which includes sealing means and which functions as the actual valve element. The second element of the valve 20 is a static seal ring 24 which acts both as a seal between upper and lower housing elements (not shown in Figures 1 and 2) and as a rigid support structure from which the valve disc 22 may be suspended. The third element is a thin support web 26 extending between the inner diameter of the static seal ring 24 and the outer diameter of the valve disc 22. The support web is used both to support the valve disc 22 in the proper operating location within housing elements and to bias the valve disc 22 to a closed position which a preselected force in the proper direction may be overcome to open the valve 20.

The valve 20 is quite small, typically having a diameter of approximately 0.20 - 0.75 inches (5.1 - 19.1mm). In the preferred embodiment shown, a valve 20 will be described herein by way of example which has a diameter of 0.33 inches (8.4mm). It will be recognised by those skilled in the art that the teachings of the present invention are equally applicable to valves of differing sizes for use in

such medical devices.

The valve disc 22 is relatively thick to prevent it from exhibiting a significant amount of flexure, particularly under situations when a high pressure in the direction opposite to normal flow would otherwise tend to cause a deflection. It will be appreciated by those skilled in the art that infusion pumps have a relatively small pump displacement, and therefore even a small amount of flexure by the valve disc 22 during pumping would result in both a significant reduction in volumetric efficiency and in an imprecise amount of medication being delivered, making the pump unsuitable for the medical use for which is is intended. In the example used herein, the valve disc 22 has a diameter of 0.12 inches (3.0mm) and a thickness of 0.025 inches (0.635mm)

As used throughout this disclosure, the term "top" of the valve 20 shall be used to mean the side from which fluid originates, and the term "bottom" of the valve 20 shall mean the side of the valve 20 from which fluid leaves as it passes through the valve 20. The side shown in the plan view of Figure 1 is the top side of the valve 20, and the side shown in the plan view of Figure 3 is the bottom side of the valve 20. The top side is shown in Figure 2 at the top of the figure when viewed in the conventional manner, and the bottom is likewise shown at the bottom of the figure.

The valve 20 has on its bottom side four protruding circular ridges or bumps 28, as shown best in Figure 3. The four bumps 28 are mounted around and extended from the periphery of the valve disc 22 on the bottom side of the valve disc 22. They are evenly distributed around the bottom of the valve disc 22, at ninety degree intervals. The purpose of the bumps 28 is to prevent the valve disc 22 from bottoming out and closing off the fluid path as will be discussed later in this specification.

The valve disc 22 has on the top side of the valve 20 from which fluid originates a dynamic sealing ridge 30, shown best in Figures 1 and 2. The dynamic sealing ridge 30 is generally cylindrical and extends upwards from the outside edge of the valve disc 22. The dynamic sealing ridge 30 extends 0.01 inches (2.54mm) above the surface of the valve disc 22 in the valve shown, and has a rounded top surface for enhanced sealing characteristics.

It will of course be appreciated by those skilled in the art that the shape of the valve disc 22 may be other than circular as shown herein. Additionally, the configurations of the bumps 28 or the sealing ridge 30 may be different, the designs discussed above merely representing the preferred embodiment.

The static seal ring 24 is located concentrically around the valve disc 22, and functions to support and locate the valve disc 22 in position. The static seal ring also functions as a gasket or an 0-ring to seal the space between the two housing portions, as will become more evident below in conjuction with the discussion of Figures 3 and 4. It is important to note that while the cross-sectional configuration of the static seal ring 24 shown in Figure 2 is the preferred embodiment, other configurations are possible. The static seal ring must present both a convenient sealing design and a structurally sound base from which the valve disc 22 is supported. The U-shaped cross-section static seal ring 24 shown in Figure 2 accomplishes both objectives admirably.

The thin support web 26 is used to support the valve disc 22 from the static seal ring 24, with the valve disc being capable of movement in essentially one direction only ie up and down. Since the entire valve 20 is constructed of elastomeric material, it will be appreciated that the web 26 will tend to bias the valve disc 22 to the position shown in Figure 2 when no outside forces are applied to the valve 20. In this position the top surface of the static seal ring 24 and the support web 26 are entirely planar, with the dynamic sealing ridge and a portion of the valve disc 22 protruding above this plane.

By manufacturing the valve 20 with uniform dimensions, the force, and hence the fluid pressure, required to displace the valve disc 22 will be highly repeatable. Since the fluid pressure required to supply this force is to be very small, ie on the order of 0.1 PSI (70.3kg/m^2) it will be appreciated that the support web must be very thin.

An additional factor is the use in the valve 20 of the present invention of a plurality of apertures 32 through the support web, the apertures 32 being arranged uniformly around the circumference of the valve disc 22. In the preferred embodiment shown there are 10 apertures 32 in the support web 26, each aperture 32 having a diameter of 0.042 inches (1.07mm). Since the outer diameter of the support web 26 where it is connected to the static seal ring 24 is 0.25 inches (6.35mm) in the preferred embodiment, the apertures remove a substantial portion of the support web 26, thereby diminishing the force and the fluid pressure necessary to displace the valve disc. The practical effect of the apertures 32 is that the support web 26 may be made thicker, which in the manufacturing sense makes the valve 20 both easier and more inexpensive to fabricate. of course, the apertures 32 also serve the purpose of allowing passage of the fluid entering the valve 20 when the valve disc 22 is open.

It will be appreciated that the valve 20 may be manufactured by moulding procedures well known in the art, such as but not limited to injection moulding or transfer moulding, with the valve 20

illustrated being manufactured as a one piece construction. The valve is typically moulded of a medical grade elastomer such as silicone rubber. A critical design criterium is the hardness of the elastomer, which is a compromise between conflicting design considerations.

The static seal ring 24 must have a low stress relaxation characteristic in order to form a good seal after an extended shelf life. A durometer hardness of 30 to 70 on the Shore A scale encompasses the outer limit's on hardness of the material used for the valve 20, with the hardness in the preferred embodiment being between 40 and 50 on the Shore A scale.

With the construction of the valve 20 being accomplished in sufficient detail, the installation of a valve 20 in the two housing portions is illustrated in Figure 4. The static seal ring 24 of the valve 20 is inserted into a circular seal retaining slot 40 in a lower housing portion 42. The retaining slot 40 is of sufficient depth to accept the portion of the static seal ring 24 in a sealing manner.

An upper housing portion 44 is then lowered into position over the valve 20 and the lower housing portion 44, and secured in position by any of number of techniques well known in the art, such as by snapping the upper housing portion 44 onto the lower housing portion 42. The installation of the upper housing portion 44 onto the lower housing portion will also compress the static seal ring 24 to form an excellent seal between the upper housing portion 44 and the lower housing portion 42 at the location of the static seal ring 24.

Also illustrated in Figure 4 is an optional circular protruding ridge 45, which may be formed on the upper housing portion in a manner whereby the circular protruding ridge 45 will be located over a central portion of the top of the static seal ring 24 to ensure an even better seal. It should be noted that with the possible exception of the protruding ridge 45, the side of the upper housing portion 44 facing the valve 20 is flat, thereby accomplishing one of the objects of the present invention.

Centrally located above the valve disc 22 and within the dynamic sealing ridge 30 is an inlet aperture 46, through which fluid may be admitted to the valve. Since the side of the upper housing portion 44 facing the valve 20 is flat, it will be appreciated that the installation of the upper housing portion 44 over the valve 20 causes the dynamic sealing ridge 30 and the valve disc 22 to be moved downwardly, thereby prestressing the support web 26 and preloading the valve 20 in a closed position. The pressure differential must reach the threshold value in order to open the valve 20 by forcing the valve disc 22 and the dynamic sealing ridge 30 away from the upper housing portion 44. In the preferred embodiment described herein, the preload requires only a minimal break pressure to open the valve, typically about 0.1 PSI (70.3kg/m^2). It is important that the material of the valve 20 should have characteristics such that this prestressing of the valve 20 does not result in stress relaxation by the material, as discussed above.

It will be noted that the design of the valve 20 on the inlet side requires and allows only a very small volume of fluid to be stored in the cavity formed between the top of the valve disc 22, the interior of the dynamic sealing ridge 30, and the side of the upper housing portion 44 facing the valve 20. It is important to minimise the volume contained within this area on the inlet side of the valve 20 when the valve 20 is used as the valve 18B at the outlet side of the pump 14 shown in Figure 6.

The design of the valve 20 also allows this volume to be minimised on the outlet side of the valve 20. Referring again to Figure 4, a web support 48 is integrally fashioned in the lower housing portion radially inside the seal retaining slot 40, with the web support forming the interior side of the seal retaining slot 40. As its name implies, the web support also extends inwardly from the seal retaining slot slightly to support a small portion of the support web 26, in the process slightly increasing the force required to open the valve 20.

An additional function of the web support 48 is to minimise the volume in the chamber outside of the dynamic sealing ridge 30 and between the upper housing portion 44 and the lower housing portion 42, this chamber being on the outlet side of the valve 20. The valve chamber floor 50 is located beneath the valve disc 22 and an outlet aperture 52 is located in the valve chamber floor 50. The web support may be larger than depicted in Figure 4 so long as it does not obstruct the valve disc 22 or the flow of fluid through the apertures 32 and around the valve discs 22. The web support 48 therefore minimised the volume contained on the outlet side of the valve 20, which is important when the valve 20 is used as the valve 18A at the inlet side of the pump 14 shown in Figure 6.

Since the force needed to open the valve 20 is very small, it is important to prevent a situation where a high inlet pressure could force the valve disc 22 to the valve chamber floor 50, thereby obstructing the outlet aperture 52 and the flow through the valve 20. The four protruding circular bumps 28, discussed above in conjuction with Figures 2 and 3, extend away from the bottom side of the valve disc 22 to prevent the valve disc 22 from blocking the outlet aperture 52 even under the conditions described above. The spaces between the bumps 28 and the facing surfaces of the valve disc 22 and the floor 50 of the lower housing

portion 42 thereby provide a fluid path even when the valve disc 22 is forced downwards by excessive force.

Alternatively, rather than having the bumps 28 moulded into the bottom of the valve disc 22, apparatus for preventing the valve disc 22 from blocking the outlet aperture 52 under the conditions described above could be located on the floor 50 of the lower housing portion 42. The bottom side of the valve disc 22 would not have the protruding bumps 28 but rather would be essentially flat with a rounded bottom edge. As shown in Figures 7 and 8, one or more valve stop ribs 54 which protrude from the floor 50 of the lower support portion 42 prevent the valve disc 22 from bottoming out and obstructing the outlet aperture 52. The space between the valve stop ribs 54 would thereby provide a fluid path when the valve disc 22 is against the valve stop ribs 54.

The spring action of the support web 26 will maintain the dynamic sealing ridge 30 of the valve disc 26 against the upper housing portion 44 as shown in Figure 4 when there is no fluid pressure, when the pressure differential across the valve is less than the break pressure, and when the pressure on the outlet side of the valve 20 is greater than the pressure on the inlet side of the valve 20. When the pressure on the inlet side of the valve 20 is greater than the pressure on the outlet side of the valve 20 by a value at least that of the break pressure, the valve 20 will open as shown in Figure 5, allowing fluid to flow in the inlet aperture 46, around the dynamic sealing ridge 30, through the apertures 32 in the support web 26, and out the outlet aperture 52.

The support web 26 will act to return the valve 20 to a closed position when the pressure across the valve 20 drops below the break pressure. The valve 20 is highly resistant to reverse flow since the valve disc 22 is relatively thick to prevent substantial deflection, thereby maintaining the dynamic sealing ridge 30 tightly against the upper housing portion 44.

It is therefore apparent that the design of the valve 20 to have a desired break pressure is determined by three factors. First, the thicker the support web, the higher the spring rate and the greater the break pressure of the valve 20. Secondly, the apertures 32 in the support web act to reduce the spring rate and the break pressure of the valve 200 as the number and size of the apertures increase. Finally, the height by which the dynamic sealing ridge 30 projects above the support web 26 provides an offset which determines the preload of the valve disc 33 and the dynamic sealing ridge 30 against the upper housing portion 44.

The valve 20 of the present invention is highly precise, and may be economically manufactured. It is suitable for use in medical devices since it is precise, has good shelf and operating lives, and is made of medical grade materials. The valve 20 has a very small break pressure, yet it seals tightly when this break pressure is not met. It may be used in conjunction with a flat top surface (the upper housing portion 44), thereby making construction of a more economical infusion pump possible and making practical an inexpensive disposable pump with positive valve operation. The present invention thereby represents a valuable and highly desirable improvement in the art, while affording no relative disadvantages.

Claims

1. A passive one way valve assembly for medical applications which comprises a valve member (20) located between a first housing member (44) having an inlet (46) and a second housing member (42) having an outlet (52), the valve member (20) of one piece manufacture including a circular valve disc (22), a static seal ring (24) surrounding the valve disc (22), and a resilient support means (26) supporting the valve disc (22) from the seal ring (24), characterised by an annular dynamic sealing ridge (30) protruding from the top surface of the valve disc (22) which engages the first housing member (44) thereby deforming the resilient support means (26), the resilience of the support means (26) in turn serving to bias the sealing ridge (30) against the first housing member (44) thereby closing the inlet (46).

2. A valve assembly as claimed in Claim 1 characterised in that the valve member (20) is manufactured of an elastomeric material of medical grade.

3. A valve assembly as claimed in Claim 1 or Claim 2, characterised in that the dynamic sealing ridge (30) has a rounded top surface to enhance its sealing characteristics.

4. A valve assembly as claimed in any preceding claim, characterised in that the support means is in the form of a relatively thin supporting web (26).

5. A valve assembly as claimed in Claim 4, characterised in that the web (26) extends from a location substantially at the top of the static seal ring (24) to the valve disc (22) at a height not exceeding the top of the valve disc (22).

6. A valve assembly as claimed in Claim 4 or Claim 5, characterised in that the web (26) is

substantially flat.

7. A valve assembly as claimed in Claim 4, Claim 5 or Claim 6, characterised in that the support web (26) has a plurality of apertures (32) to allow the passage of fluid therethrough.

8. A valve assembly as claimed in any preceding Claim, characterised in that the static seal ring (24) is sufficiently large so as to be relatively rigid in supporting the valve disc (22).

9. A valve assembly as claimed in any preceding Claim, characterised in that the support means (26) has a portion adjacent the static seal ring (24) which is arranged to be supported by a web support portion (48) which forms part of the lower housing member (42).

10. A valve assembly as claimed in any preceding Claim, characterised by at least one bump (28) extending below the bottom surface of the valve disc (22).

11. A valve assembly as claimed in any preceding Claim, characterised in that the first housing member (44) has a substantially flat surface which is in contact with the sealing ridge (30) when the outlet (52) is closed.

Patentansprüche

1. Passive Einwegventilanordnung für medizinische Anwendungen, welche ein Ventilelement (20) umfaßt, welches sich zwischen einem ersten Gehäuseelement (44) mit einem Einlaß (46) und einem zweiten Gehäuseelement (42) mit einem Auslaß (52) befindet, wobei das einstückig ausgebildete Ventilelement (20) einen Kreisförmigen Ventilteller (22), einen statischen Abdichtring (24), der den Ventilteller (22) umgibt, und ein nachgiebiges Abstützmittel (26), umfaßt, das den Ventilteller (22) gegenüber dem Abdichtring (24) abstützt, **gekennzeichnet durch** eine ringförmige dynamische Abdichtrippe (30), die von der oberen Fläche des Ventiltellers (22) vorsteht und die das erste Gehäuseelement (44) erfaßt, wodurch das nachgiebige Abstützmittel (26) deformiert wird, wobei die Nachgiebigkeit des Abstützmittels (26) ihrerseits dazu dient, die Abdichtrippe (30) gegen das erste Gehäuseelement (44) vorzuspannen, wodurch der Einlaß (46) geschlossen wird.

2. Ventilanordnung nach Anspruch 1, dadurch gekennzeichnet, daß das Ventilelement (20) aus einem elastomeren Material medizinischer Qualität hergestellt wird.

3. Ventilanordnung nach Anspruch 1 oder 2, **dadurch gekennzeichnet, daß** die dynamische Abdichtrippe (30) eine abgerundete obere Fläche hat, um ihre Abdichteigenschaften zu verbessern.

4. Ventilanordnung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** das Abstützmittel die Form eines relativ dünnen Abstützstegs (26) hat.

5. Ventilanordnung nach Anspruch 4, **dadurch gekennzeichnet, daß** der Steg (26) sich von einer Stelle im wesentlichen an der Oberseite des statischen Abdichtrings (24) aus zu dem Ventilteller (22) in einer Höhe erstreckt, die die Oberseite des Ventiltellers (22) nicht übersteigt.

6. Ventilanordnung nach Anspruch 4 oder 5, **dadurch gekennzeichnet, daß** der Steg (26) im wesentlichen flach ist.

7. Ventilanordnung nach Anspruch 4, 5 oder 6, **dadurch gekennzeichnet, daß** der Abstützsteg (26) eine Vielzahl von Öffnungen (32) aufweist, um den Durchgang von Fluid dort hindurch zu gestatten.

8. Ventilanordnung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** der statische Abdichtring (24) ausreichend groß ist, um beim Abstützen des Ventiltellers (22) relativ starr zu sein.

9. Ventilanordnung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** das Abstützmittel (26) einen Bereich in der Nähe des statischen Abdichtrings (24) aufweist, der angeordnet ist, um durch einen Stegabstützbereich (48) abgestützt zu werden, der Teil des unteren Gehäuseelements (42) bildet.

10. Ventilanordnung nach einem der vorhergehenden Ansprüche, **gekennzeichnet durch** mindestens eine Erhebung (28), die sich unterhalb der unteren Fläche des Ventiltellers (22) erstreckt.

11. Ventilanordnung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** das erste Gehäuseelement (44) eine im wesentliche flache Oberfläche aufweist, die in Kontakt mit der Abdichtrippe (30) steht, wenn der Auslaß (52) geschlossen ist.

Revendications

1. Assemblage comportant une valve unidirectionnelle passive pour applications médicales comprenant un élément de valve (20) situé entre un premier élément de boîtier (44) ayant une entrée (46) et un second élément de boîtier (42) ayant une sortie (52), l'élément de valve (20) fabriqué en une pièce comprenant un disque de valve circulaire (22), une bague de joint statique (24), entourant le disque de valve (22) et un dispositif de support élastique (26) supportant le disque de valve (22) à partir de la bague de joint (24), caractérisé par un rebord jointif dynamique annulaire (30) saillant à la face supérieure du disque de valve (22) qui s'engage dans le premier élément de boîtier (44), déformant ainsi le dispositif de support élastique (26), l'élasticité du dispositif de support (26) permettant alors d'appuyer le rebord jointif (30) contre le premier élément de boîtier (44) fermant ainsi l'entrée (46).

2. Assemblage de valve tel que revendiqué dans la revendication 1, caractérisé en ce que l'élément de valve (20) est fabriqué dans un matériau élastomère de qualité médicale.

3. Assemblage de valve tel que revendiqué dans la revendication 1 ou la revendication 2, caractérisé en ce que la face supérieure du rebord jointif dynamique (30) est arrondie afin d'améliorer ses caractéristiques d'étanchéité.

4. Assemblage de valve tel que revendiqué dans l'une quelconque des revendications précédentes, caractérisé en ce que le dispositif de support est sous forme d'une toile de support relativement mince (26).

5. Assemblage de valve tel que revendiqué dans la revendication 4, caractérisé en ce que la toile (26) s'étend entre une position située presqu'en haut de la bague de joint statique (24) et le disque de valve (22) à une hauteur n'excédant pas le haut du disque de valve (22).

6. Assemblage de valve tel que revendiqué dans la revendication 4 ou la revendication 5, caractérisé en ce que la toile (26) est pratiquement plate.

7. Assemblage de valve tel que revendiqué dans la revendication 4, la revendication 5 ou la revendication 6, caractérisé en ce que la toile de support (26) comporte plusieurs orifices (32) permettant le passage de fluide au travers.

8. Assemblage de valve tel que revendiqué dans l'une quelconque des revendications précédentes, caractérisé en ce que la bague de joint statique (24) est suffisamment large pour être relativement rigide en supportant le disque de valve (22).

9. Assemblage de valve tel que revendiqué dans l'une quelconque des revendications précédentes, caractérisé en ce que le dispositif de support (26) a une partie adjacente à la bague de joint statique (24) qui est disposée de façon à être supportée par une portion de support de toile (48) qui forme une partie de l'élément de boîtier inférieur (42).

10. Assemblage de valve tel que revendiqué dans l'une quelconque des revendications précédentes, caractérisé par au moins une bosse (28) située en dessous de la face inférieure du disque de valve (22).

11. Assemblage de valve tel que revendiqué dans l'une quelconque des revendications précédentes, caractérisé en ce que le premier élément de boîtier (44) a une surface pratiquement plate qui est contact avec le rebord jointif (30) lorsque la sortie (52) est fermée.

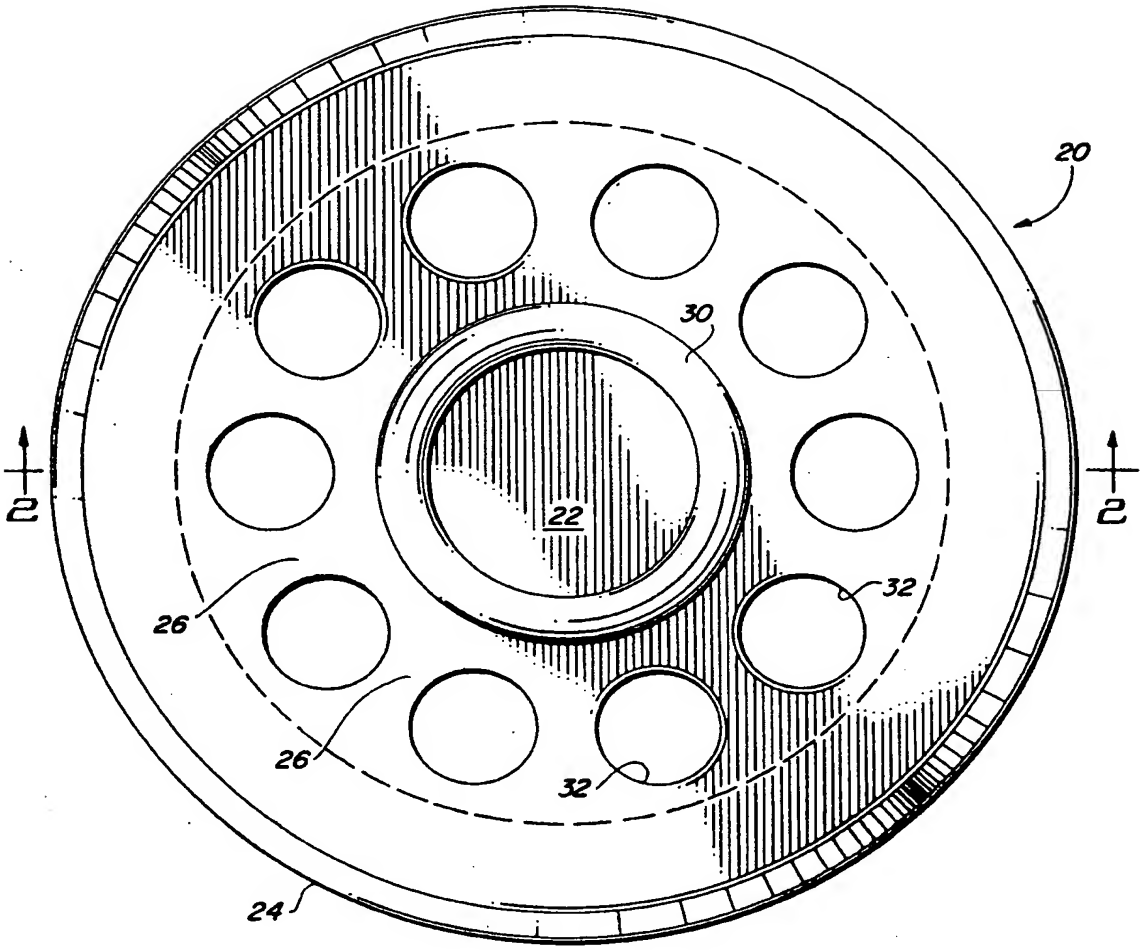

FIG. 1

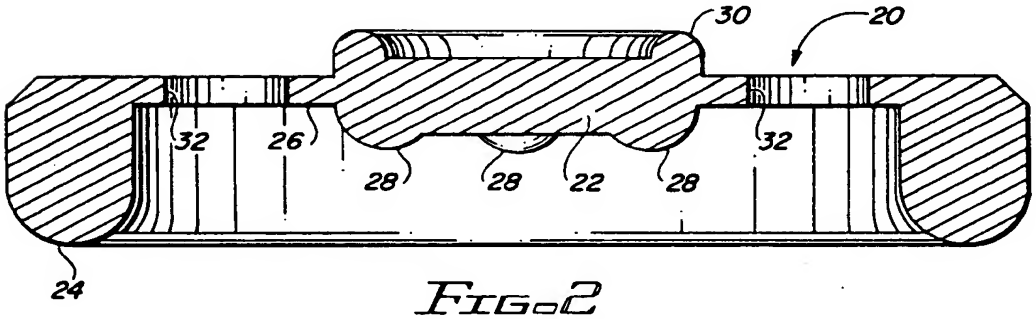

FIG. 2

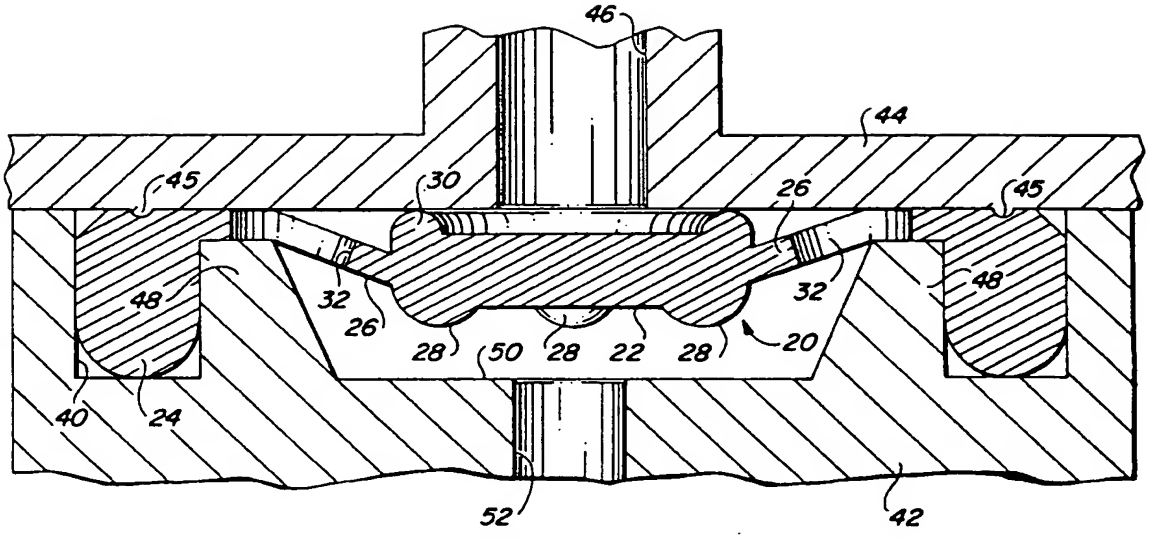
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FIG.4

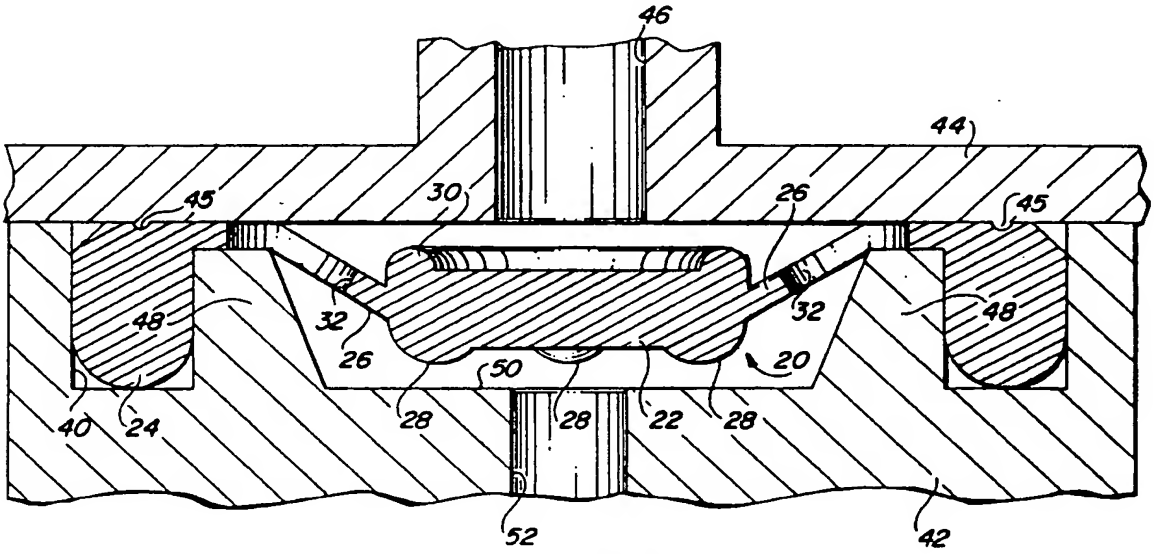
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FIG.5

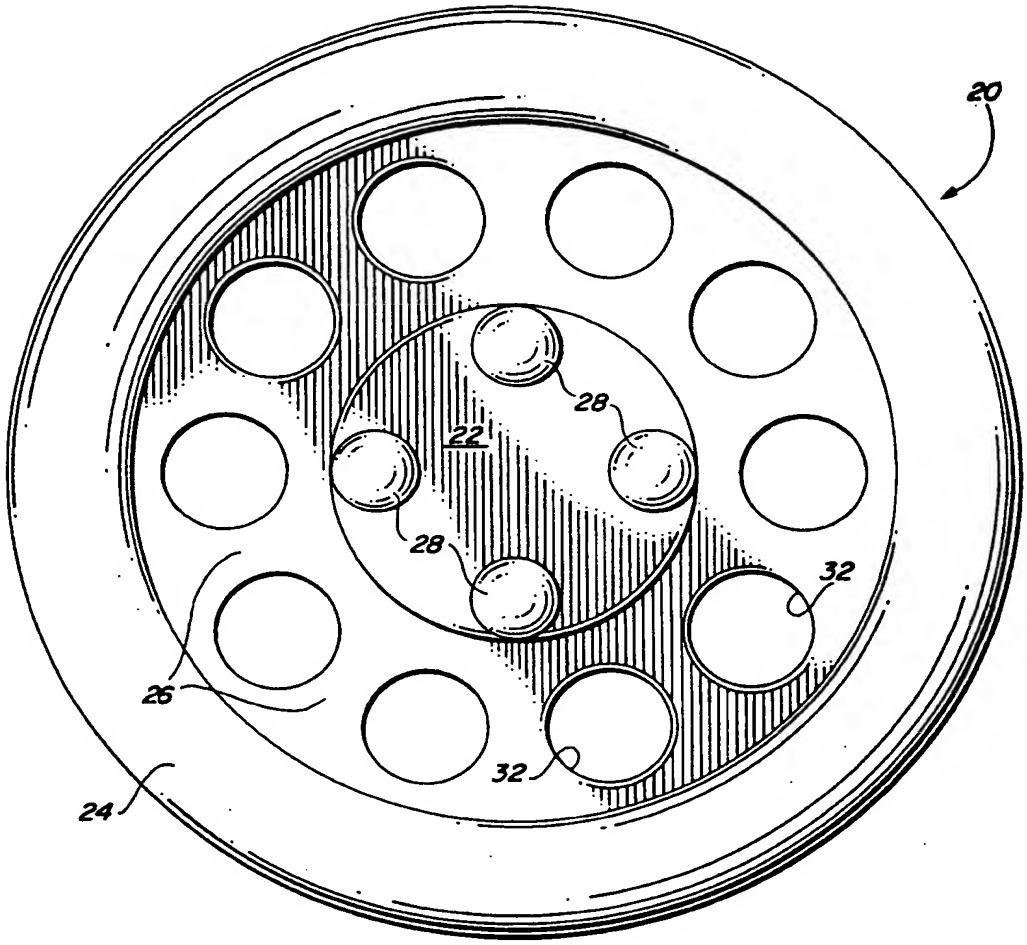
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FIG. 3

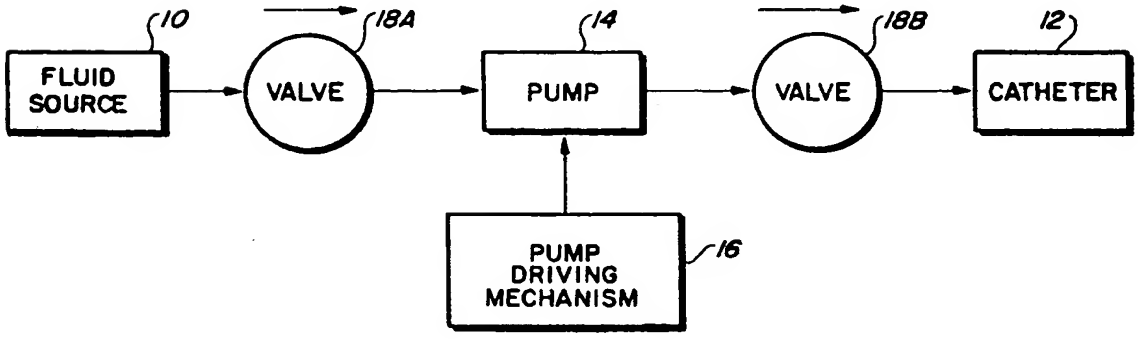
10
18A
14
18B
12
FLUID SOURCE
VALVE
PUMP
VALVE
CATHETER
PUMP DRIVING MECHANISM
16

FIG. 6

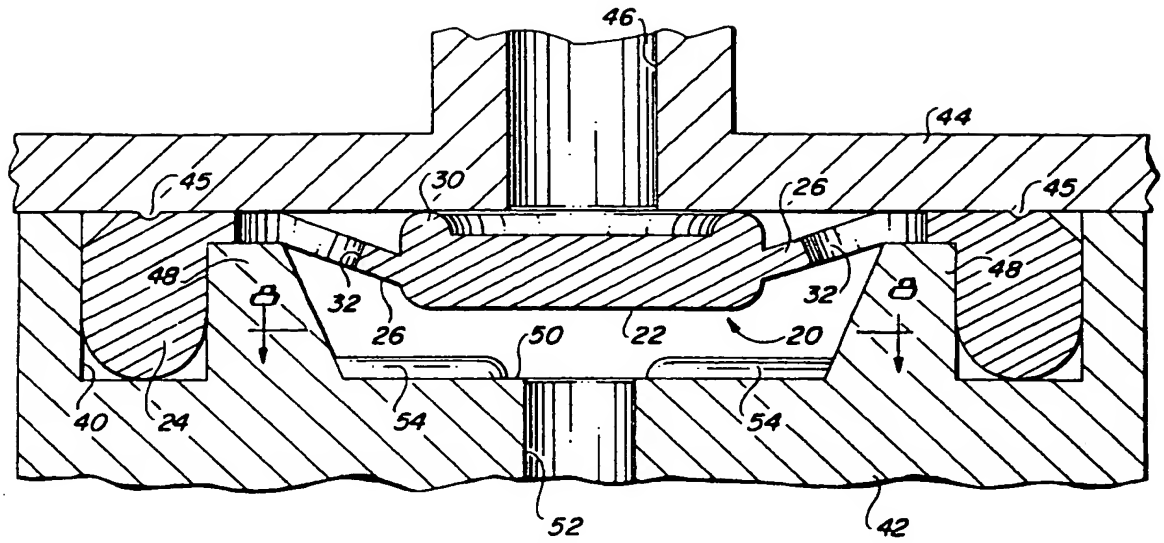
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FIG-7

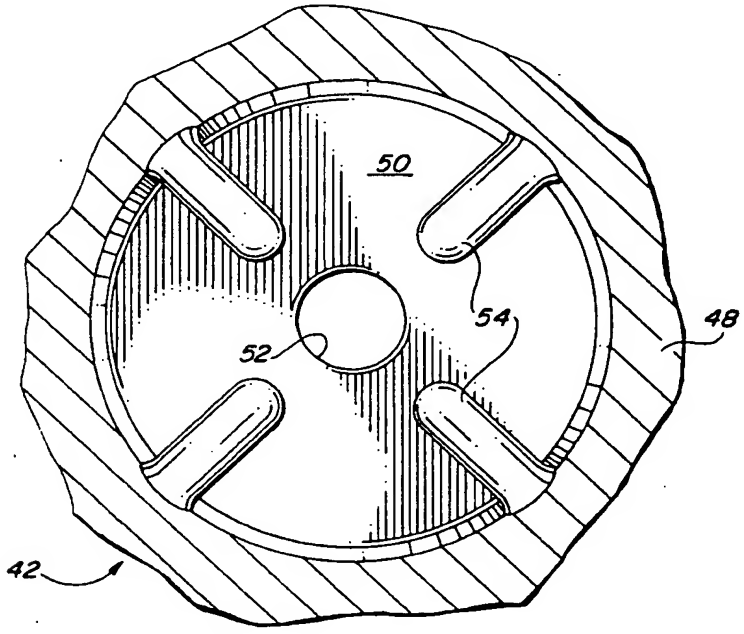
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FIG-8